

- 27. Canceled
- 28. Canceled
- 29. Canceled
- 30. Canceled
- 31. Canceled
- 32. Canceled
- 33. Canceled
- 34. The composition as set forth in claim 1 wherein said carrier consists / 5 essentially of an antioxidant.
- 35. The composition as set forth in claim 34 wherein said antioxidant consists essentially of an ascorbate.
- 36. The composition as set forth in claim 34 wherein the antioxidant consists essentially of nordihydroguiaretic acid.
- 37. The composition as set forth in claim 1 wherein the metal comprises a heavy metal.
  - 38 Canceled

### **REMARKS**

Claims 1-7, 14-21 and 34-37 are pending in the application. Claims 22-33 and 38 have been canceled. Claims 1-4 have been amended.

### Restriction/Election

Claims 23-33 and 38 have been canceled without prejudice due to the Examiner's requirement that these claims must be cancelled. Applicant's

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attorney respectfully submits that the required cancellation of claim 38 should be rescinded and the claim reinstated because the recited metals in the group consisting of copper, iron, manganese molybdenum and cobalt are all heavy metals in accord with Applicant's election because these metals all have an atomic weight greater than sodium, and all may have an oxidation state of +2.

#### Claim Amendments

Claim 1 has been amended to correct a misspelling of 8-hydroxyquinoline, which was introduced as "8-hydrozyquinoline" in the response dated March 27, 2000. Claims 2 and 4 have been amended to recite a proper antecedent for the "escharotic chelatable metal agent." Claim 3 has been amended to depend from claim 2, which provides an antecedent for "said ratio." None of these amendments comprise new matter.

## The §103 rejection of claims 1-7, 14-22 and 34-37 over WO/03805

This rejection is based upon the disclosure, in WO/03805 on pages 9 and 119, the quercetin may be mixed with zinc halide for the prevention of tumor cells. Nevertheless, WO/03085 is devoid of ant teaching or suggestion as to the use of 8-hydroxyquinoline in combination with an escharotic chelatable metal agent for use in treating cancers or precancerous lesions.

The recitation of quercetin as a source of 8-hydroxyquinline in the former claim 22 has now resulted in the cancellation of that claim because quercetin does not contain 8-hydroxyquinoline. Prior remarks on page 13 of the response dated December 26, 2000 as to quercetin containing 8-hydroxyquinoline were in error and resulted from a miscommunication between inventor Russell Jordan,

the other inventors, and Applicants' attorney. A Declaration from Russell T. Jordan is attached to explain the miscommunication.

As is apparent from the Jordan Declaration, quercetin is in a different class of materials than is 8-hydroxyquinoline. The uses of quercetin versus 8-hydroxyquinoline produce results that differ in kind because the claimed composition including 8-hydroxyquinoline works to eradicate a broader array of lesions and is generally more effective against such lesions.

As the Examiner has stated on page 3 of paper number 12, no examples exist for efficacy of a single product against cancerous lesions or precancerous lesions generally. The broad spectrum of applicability, as is presently claimed, is substantial evidence of nonobviousness because the WO/030805 publication did not teach a wide range of lesions that may be eradicated, and because the WO/030805 publication does not teach or suggest the use of 8-hydroxyquinoline which resides in a different class of chemical than does quercetin.

WO/030805 constitutes nonanalagous art with respect to the present claims because the publication is completely silent as to the use of 8-hydroxyquinoline in combination with a metal agent.

Accordingly, the claim 1, as well as the respective dependant claims, are nonobvious over WO/03805.

The §103 rejection of claims 1-7, 14-22 and 34-37 over EP 0506207 and GB 1215676 for reasons stated in Paper No. 12.

The Examiner observes that Applicants prior remarks in response to this rejection are noted, but invites a side-by-side comparison. A large amount of

time is required to produce side-by-side comparisons, such as the one that the Examiner has requested to see, and the required time to perform these tests has been the primary reason for delay in responding to the present office action.

Test results have been compiled showing side-by-side comparison between the claimed composition using zinc chloride as the source of the metal, a composition substituting quercetin for 8-hjydroxyquinoline in the claimed composition, and a composition from which zinc chloride has been omitted. The tests were performed on equine sarcoids, and in each case only the claimed composition worked to eradicate the lesion.

The tests, though complete, are still being processed for formal signing.

Applicants' attorney expects to be able to provide a Declaration from Barbara

Page, DVM, attesting to the tests and the comparative results within a few days.

The test results and associated Declaration could not be provided with this amendment due to the necessity of responding by today to the office action dated May 3, 2001.

Inasmuch as the rejection incorporates the Examiner's prior remarks, and invites an additional comparison. Applicants' attorney refers to the remarks submitted on December 26, 2001 (pages 7-12) in response to Paper 12 and incorporates these remarks in the present response. In summary of these remarks, EP 0506207 and GB 1,215,676 teach the use of dilute concentrations, e.g., less than 1% by weight, that are far below the range that is presently claimed. These other patents pertain to antifungal compositions, and constitute nonanalogous art with respect to cancer drugs.

It appears from remarks on page 3 of the present office action that the Examiner would be persuaded by a showing of enhanced utility in a side-by side comparison to Supplement the Potestio Declaration, as will soon be provided in the forthcoming Declaration from Dr. Page.

# The §112 rejection of claims 1 and 7

The present office action asserts on page 3 that these claims are drawn to the same composition, i.e., the claims do not differ in scope. Applicant's attorney respectfully traverses this rejection because the claims do differ in scope. Claim 1 merely recites that the claimed composition has "a capacity for treating" lesions selected from the group, whereas claim 7 recites the actual presence of necrotic tissue in combination with the composition, i.e., claim 7 differs in scope by including the necrotic tissue. This distinction differs in scope, for example,

The amended claims are patentable for the above reasons. No additional fees are seen to be due. However, if any additional fees are due, the Commissioner is authorized to charge them to deposit account No. 12-600.

Respectfully submitted, LATHROP & GAGE

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